



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Exemption of the Advanced Research Projects Agency for Health (ARPA-H) from Policies and Requirements of the National Institutes of Health (NIH)

AGENCY: Advanced Research Projects Agency for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the U.S. Department of Health and Human Services (HHS) has statutory authority to exempt the Advanced Research Projects Agency for Health (ARPA-H) from certain policies and requirements of the National Institutes of Health (NIH) as necessary and appropriate to ensure ARPA-H can most effectively achieve its statutorily specified goals. Pursuant to such authority, and for the reasons stated herein, the Secretary is giving notice that he intends to exempt ARPA-H from all NIH policies and requirements subject to the limitations and condition stated herein.

FOR FURTHER INFORMATION CONTACT: Thomas Libert, 240-731-3874, tom.libert@arpa-h.gov

SUPPLEMENTARY INFORMATION: This notice follows 87 FR 32174, published on May 24, 2022. The Consolidated Appropriations Act, 2023 (P.L. 117-328, enacted on December 29, 2022) includes authorizing language for ARPA-H. Notably, section 499A of the Public Health Service Act (PHSA), as added by section 2331(a) of the Consolidated Appropriations Act, 2023, establishes ARPA-H within NIH and provides that the Director, ARPA-H, shall report to the Secretary of HHS.

Subparagraph (A) of section 499A(a)(3) provides that the Secretary may exempt ARPA-H from NIH policies and requirements that are in effect on the day before the enactment of section 499A as necessary and appropriate to ensure ARPA-H can most effectively achieve its statutorily specified goals, except as otherwise provided for in section 499A and subject to the requirements

of subparagraph (B). Subparagraph (B) of section 499A(a)(3) provides that not later than 90 days after the date of enactment of section 499A, the Secretary shall publish a notice in the *Federal Register* describing the specific NIH policies and requirements from which the Secretary intends to exempt ARPA-H, including a rationale for such exemptions.

Pursuant to section 499A(a)(3) of the PHSA, notice is hereby given that I intend to exempt ARPA-H from all policies and requirements of the NIH that were in effect on the day before the enactment of section 499A, that is, on December 28, 2022.

The exemption is necessary and appropriate to ensure ARPA-H can most effectively achieve its statutorily specified goals and consistent with prior actions for the following reasons:

- The mission of ARPA-H is complementary to NIH, but its business model is distinct and separate. To succeed at its mission to realize transformative health solutions, ARPA-H must establish a unique culture and distinct and separate business and operations processes, including its own policies and requirements.
- On April 15, 2022, I transferred ARPA-H to NIH as authorized by title II of division H of the Consolidated Appropriations Act, 2022 (P.L. 117-103, enacted on March 15, 2022) and delegated to the Director, NIH, certain authorities for the purpose of carrying out ARPA-H (87 FR 23526). As a condition of the delegation, I specified that NIH may not subject ARPA-H to NIH policies.
- As noted, section 499A of the PHSA establishes ARPA-H within NIH and provides that the Director, ARPA-H, shall report to the Secretary. In the Joint Explanatory Statement (168 Cong. Rec. S8895, 2022), Congress signaled its intent for ARPA-H to establish its own culture, procedures, and policies:

The agreement strongly encourages HHS to collaborate with the Defense Advanced Research Projects Agency (DARPA) to develop the foundational policies, procedures, and staff training for ARPA-H employees. The agreement believes ARPA-H will require a very different culture and mission than NIH's other 27 Institutes and Centers.

ARPA-H shall continue to be subject to all policies and requirements of HHS. All major policy, programmatic, and operational decisions proposed by ARPA-H shall continue to come to the Secretary for approval.

The exemption is subject to the following condition:

- Where ARPA-H identifies a need to develop a policy or requirement to fulfill its mission, it shall rely upon NIH policies and requirements until such time as ARPA-H develops its own policies and requirements as appropriate.

Xavier Becerra,

Secretary of Health and Human Services.

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